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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,401	11/21/2005	Hiroshi Tsuchita	Q88294	1465

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
06/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,401	TSUCHITA ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,16,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,16,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received March 12, 2009.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2-4, 7-15, 17-19, 22-23 are canceled. Claims 1, 5-6, 16, 20-21 are currently under examination.

Priority: The request for priority to JAPAN 2002-350200, filed December 2, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-6, 16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantman (US 4687782; IDS; previously cited). Brantman discloses a composition consisting essentially of carnitine, isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein, soy protein, lactalbumin (col. 7 lines 30-50), adapted for use with water as a diet supplement for facilitating the adaptation of skeletal muscle and liver to a program of strenuous exercise. Brantman further discloses a method of supplementing the diet of an athlete by having the athlete drink a solution consisting essentially of leucine, isoleucine, valine, glutamine, and a whey

protein, and having the athlete drink the solution (col. 6 lines 42-53). In col. 4 lines 45-50, Brantman discloses numerical ranges for the amino acids used in the composition: leucine (20-45 parts), isoleucine (15-40 parts), valine (15-40 parts), glutamine (10-30 parts), carnitine (0.3-2.0 parts), wherein the relative proportions of the amino acids are preferably within 20% of the recited ranges (col. 5 lines 20-25). It should also be noted that Brantman discloses that carnitine is an amino acid that is synthesized in the body (col. 3 lines 55-63). Further, one of ordinary skill can see that out of all the amino acids used in said composition, carnitine is present in the smallest amount, i.e. 0.3 -2.0 g (col. 4 lines 45-50). Brantman does not specifically teach a composition consisting of leucine, isoleucine, valine, glutamine, and a whey protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Brantman and formulate a composition consisting of isoleucine, leucine, valine, glutamine, and a whey protein, i.e. casein (claim 1, 5-6) and administer said composition to an athlete (claim 16, 20-21). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in improving fatigue during exercise because Brantman teaches a composition consisting essentially of the branched amino acids, i.e. isoleucine, leucine, leucine, valine, glutamine, and a whey protein, which can be administered to promote muscle adaptation to strenuous exercise in a person. Regarding the motivation to exclude carnitine from said composition, it would be reasonable for one of ordinary skill to know that since Brantman discloses carnitine is synthesized in the body and its incorporation into said composition is in a very small amount when compared to the other amino acids, it would be reasonable to exclude carnitine from said composition since the body naturally synthesizes carnitine.

In their remarks, Applicants assert (1) that the recitation of "comprising" in claim 16 allows for the inclusion of additional process steps, such as the administration of another composition, Applicants note that the composition of claim 16 nevertheless "consists of" leucine, isoleucine, valine, glutamine, and a whey protein component. (2) Brantman discloses that carnitine plays a critical role in protecting against the toxic effects of ammonia (col. 3 lines 64-67). Further in this same section, Brantman discloses that "[a]mmonia is generated during catabolism of amino acids, such as occurs during strenuous exercise, and is toxic. The ready removal of ammonia from muscle is thus desirable." Further, because the BAAs in the composition of Brantman are added to "spare" muscle protein and especially muscle BAA by providing the very substrate which is being utilized at the expense of muscle mass (col. 3 lines 23-26), one of ordinary skill would readily recognize that the BAAs in the composition of Brantman, which are added and catabolized so as to "spare" catabolism of muscle BAAs, would produce toxic ammonia, and thus repair prevention of muscle fatigue. Accordingly, in view of the disclosure in Brantman of the criticality of carnitine in protecting against the toxic effects of ammonia, Brantman teaches away from producing a composition lacking carnitine. Applicants' arguments have been fully considered but they are not persuasive.

(1a) The Brantman reference has been withdrawn as a 102(b) reference over claim 16; however it is still believed to be relevant art under 103(a) as noted above.

(2a) While Brantman may disclose that carnitine plays a critical role in protecting against the toxic effects of ammonia and that the ready removal of ammonia from muscle is thus desirable, Brantman also discloses that carnitine is an amino acid that is synthesized in the body.

Therefore, the production of carnitine by the body would naturally remove some of the ammonia from muscle. Also as noted in the 103(a) rejection above, out of all the amino acids used in said composition, carnitine is present in the smallest amount, i.e. 0.3 -2.0 g (col. 4 lines 45-50). Therefore, it would be reasonable for one of ordinary skill to recognize that carnitine can be excluded from said composition since it is synthesized by the body and its quantity in said composition does not appear to be of a significant quantity.

For at least these reasons, the Brantman reference is still believed to be relevant art under 103(a).

Claims 1, 5-6, 16, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verlaan et al. (US 7288570) as evidenced by Health Publications (October 2000). Verlaan et al. disclose the Megawhey™ product from GNC contains the essential ingredients whey, glutamine, isoleucine, leucine, valine (col. 1 lines 48-52), wherein said Megawhey™ product stimulates the production of proteins in vivo. While the Megawhey™ product contains other components, i.e. lipids, carbohydrates, calcium, potassium, taste enhancers, etc., it would be apparent to one of ordinary skill to know that the essential ingredients in said Megawhey™ product are whey protein, glutamine and the branched amino acids (isoleucine, leucine, valine) and that the other components are merely extra additives that contribute additional nutritional value to said product but are not critical to stimulating protein production in vivo.

The Health publications article is cited as evidence to note that said Megawhey™ product has been on the market since at least October 2002.

It would have been obvious to one of ordinary skill in the art at the invention was made to modify the teachings of Verlaan et al. by formulating a composition consisting of whey, glutamine, leucine, isoleucine, valine and administer said composition to an athlete (claim 1, 5-6, 16, 20-21). One of ordinary skill would be motivated to administer said composition to an athlete and expect it to be successful in improving fatigue during exercise because Verlaan et al. disclose that a Megawhey™ product containing whey, glutamine, and the branched amino acids leucine, isolecuine, valine, can stimulate protein in vivo. Regarding the motivation to exclude the other components in said Megawhey™ product, it would be reasonable for one of ordinary skill to know that the essential ingredients in said Megawhey™ product are whey protein, glutamine and the branched amino acids (isoleucine, leucine, valine) and that the other components are merely extra additives that contribute additional nutritional value to said product but are not critical to stimulating protein production in vivo.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

June 1, 2009